

# PROCEDURES FOR ROUTINE and EMERGENCY VACCINE MANAGEMENT-2014

Office/agency name

The following individuals have primary responsibility for maintaining all procedures related to the proper storage and handling of vaccines; however, ALL staff must know how to handle vaccines in the event of an emergency or when the following individuals are not available.

## VACCINE COORDINATOR DESIGNATION:

*This individual is the **primary** VFC contact for this clinic!*

\_\_\_\_\_ is the **primary** staff member responsible for vaccine management and is responsible for training other staff how to:

- Implement vaccine storage and handling procedures;
- Administer and properly record vaccines;
- Properly pack and transport vaccines in the event of an emergency,
- Educate staff if problems with inventory are noted.
- Maintaining the Storage and Handling and Vaccines for Children training log for all staff members; and,
- Updating the Vaccine Management and Emergency Plan *annually* or when staff changes.

*This individual is the designated back-up VFC contact.*

\_\_\_\_\_ is the **secondary (backup)** staff person responsible for completing the duties of the primary Vaccine Coordinator when this individual is unavailable.

## OPTIONAL:

\_\_\_\_\_ is the third **VFC contact**, or **tertiary** back-up, if neither of the above individuals is available.

## DUTIES OF THE VACCINE COORDINATOR:

In addition to the above responsibilities, the routine duties of the Vaccine Coordinator, the back-up or other designated staff are:

### A. MONITORING INVENTORY:

- Routine inventory counts are done on \_\_\_\_\_ (day of the month), with additional counts as needed.
  - If inventory problems are discovered notify the Vaccine Coordinator immediately!
- Expiration dates are checked routinely and stock rotated as needed to guarantee vaccines with shortest expiration dates are used first.
  - All staff members who administer vaccines are responsible for:
    - Using the vaccine with shortest expiration date first
    - Checking the vaccine expiration date while preparing immunizations to assure that the vaccine is not expired.
- Immediately remove boxes of expired vaccines from inventory:
  - Prepare them for return to the VFC program, if VFC supplied vaccines.
- One box of each vaccine type is opened at any one time.
  - Multiple open boxes of the same vaccine must be reported to the Vaccine Coordinator.
  - This ensures that short dated doses are used first to minimize vaccine wastage.
- Guarantee vaccines are kept in their original box with lids attached and closed:

- Prevent exposure to light,
- Provide an extra layer of thermal protection to the vaccines, and
- Prevent lot numbers of vaccines from becoming mixed decreasing the possibility of administering either expired vaccines or the wrong vaccine.
- Ensure vaccines are stored in the middle of the unit, away from walls, floors, and cold air vents, and not on the door, and there are spaces between boxes to allow good air circulation.
- Ensure there is never food or drinks stored with vaccines.
- Vaccine inventories are separated and easily identified as either VFC or Private.
- Contact Nicole Ortiz at 303-692-2700 **three months before the expiration date** if there are vaccines in stock that will not be used before they expire.

## B. ORDERING VACCINES:

- VFC supplied vaccines are ordered at most **once a month**
- A 30-45 days inventory is maintained.

**NOTE:** VFC vaccine orders must be placed by 5:00 PM on the 21<sup>st</sup> day of every month.

- VFC vaccine orders are placed via: Vaccine Ordering Module in CIIS
- Copies of orders placed will be maintained in the [redacted] file.
  - This file is located [redacted].
- Private vaccines are ordered [redacted] from [redacted].  
(frequency) (where)
- If any questions arise about inventory or vaccine costs, contact [redacted] for discussion.

## C. RECEIVING VACCINES:

- Vaccines are delivered to:  
[redacted]  
(Location: the front reception area, main office or the shipping dock, etc.)
- The person receiving a vaccine shipment must immediately notify **any** of these people to ensure proper storage of delivered vaccine:
  - [redacted], Vaccine Coordinator, phone: [redacted]
  - [redacted], Back-up Coordinator, phone: [redacted]
  - [redacted], Other responsible staff, phone: [redacted]
- The individual(s) accepting responsibility of a vaccine shipment will:
  - Inspect the package(s) and contents for damage.
  - Check the cold chain monitoring devices.
  - Check the vaccine order submitted against the packing slip.
  - Check quantity, lot number, and expiration dates of the vaccine.
  - Record the date of receipt of the vaccine on the shipping invoice.
  - Store vaccine appropriately in the refrigerator/freezer.
    - Keep VFC vaccine separate from privately purchased vaccine.
    - Use VFC labels (available from the VFC program) to identify VFC stock from private stock.
    - Never place vaccines in the door or in vegetable, fruit, or meat bins.
    - Vaccines with shortest expiration dates are rotated forward (placed in front) of newly received vaccines.
  - **Contact McKesson Specialty at 1-877-822-7746 with any discrepancy/damage within 2 hours of receiving the vaccine shipment.**



**NOTE:** If a minimum-maximum thermometer is used to monitor temperatures record the minimum and maximum temperatures on the log also, and reset the thermometer. This is done every morning.

#### **F. RETURNING EXPIRED/WASTED VFC VACCINE:**

The Vaccine Coordinator, back-up, or designee is responsible for returning vaccines to the VFC program. **NOTE:** Only non-viable vaccines will be accepted for return. This procedure is for the return of expired/wasted **VFC vaccine only**.

- Call the VFC Program at 303-692-2700 for complete instructions on doing a vaccine return, as the process changes based on information the VFC program receives from McKesson Distribution.
- Fax a completed **Vaccine Return Form** describing the incident to 303-691-6118.
  - Access this link to print a return form: [www.ColoradoVFC.com](http://www.ColoradoVFC.com) under the Forms and Materials heading
- Place the following items in a box:
  - Expired/wasted vaccine (does not need to be on ice packs).
  - A copy of the completed **Vaccine Return Form** describing the incident.
- Expired/wasted VFC vaccines must be returned *within 6 months* of expiration or wastage.

### **MAINTAINING THE COLD CHAIN:**

**PURPOSE:** To provide personnel with guidelines to ensure proper vaccine storage and handling in both daily management and emergency management of vaccines.

### **VACCINE STORAGE EQUIPMENT**

#### **A. REFRIGERATORS AND FREEZERS:**

- All vaccine storage units in this office/clinic meet CDC guidelines for storage of vaccines.
  - NO dormitory “style” units are used for vaccine storage at any time.
  - Only standard size household refrigerators/freezers with dual controls, stand-alone refrigerator and freezer, or pharmaceutical grade vaccine storage units are allowed.
- Vaccines in this office are stored in \_\_\_\_\_ located  
( total number of) refrigerator(s)/freezer(s)  
in \_\_\_\_\_  
(Location of each unit)
- The proper temperature range for the storage of vaccine is:
  - Refrigerator:
    - Between +35 and +46 Fahrenheit (F) or
    - Between +2 to +8 Celsius (C)
  - Freezer:
    - Between -58 and +5 Fahrenheit (F) or
    - Between -50 and -15 Celsius (C)
- There is a **“DO NOT DISCONNECT”** or **“DO NOT UNPLUG”** sign in place immediately next to the refrigerator/freezer electrical outlet.
  - The sign is complete with name and phone number of primary contact.
  - This contact information is updated as needed.

- New signs are obtained from the VFC program at [www.coloradovfc.com](http://www.coloradovfc.com) under the Forms and Materials heading.
- There is a **"DO NOT INTERRUPT"** sign in place at circuit breaker(s) for all units used to store vaccines.
  - The breaker(s) are located: \_\_\_\_\_.
  - (Where in the building)
  - The sign is complete with name and phone number of primary contact.
  - This contact information is updated as needed.
  - New signs can be obtained from the VFC program at [www.coloradovfc.com](http://www.coloradovfc.com) under the Forms and Materials heading.

## B. THERMOMETERS:

- The vaccine storage units have individual calibrated thermometers correctly placed on the center shelf of each refrigerator and freezer.
  - Calibration certificates for all thermometers are kept in the same file with the temperature log sheets for easy reference.
  - This file is located: \_\_\_\_\_.
- Thermometer batteries are replaced yearly.
- Thermometers are replaced when the certificate expires or if the unit is malfunctioning.
  - Order replacement thermometers from the VFC program at [www.coloradovfc.com](http://www.coloradovfc.com)
  - Allow 30 days before the certificates expire.

## C. REFRIGERATOR/TEMPERATURE ALARM SYSTEMS:

**SKIP THIS SECTION IF THERE IS NO ALARM SYSTEM!**

A temperature alarm system, which is constantly monitored by a 24 hour security company, is installed in the storage unit.

- The alarm system temperature ranges are set to allow the alarm to sound when the temperature in the unit exceeds the recommended vaccine storage temperature for longer than \_\_\_\_\_.
- (amount of time)
- When the temperature goes above or below acceptable temperatures, the alarm company initiates the following call-down list as indicated:
  - During office hours - \_\_\_\_\_ (ph. \_\_\_\_\_),  
\_\_\_\_\_ (ph. \_\_\_\_\_),
  - After hours - \_\_\_\_\_ (ph. \_\_\_\_\_),  
\_\_\_\_\_ (ph. \_\_\_\_\_),  
\_\_\_\_\_ (ph. \_\_\_\_\_).
- The alarm system is checked according to the following schedule, or as recommended by the manufacturer or system installer:  
\_\_\_\_\_.
- The alarm system is maintained by:
 

Company Name: \_\_\_\_\_  
 Contact Name: \_\_\_\_\_  
 Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

**D. PROTOCOL FOR HANDLING POTENTIALLY COMPROMISED VACCINES**

**NOTE: NEVER ASSUME VACCINES ARE COMPROMISED OR WASTED.**

- Immediately store vaccines as recommended and label vaccines as “Quarantined-DO NOT USE”.
- Contact Nicole Ortiz at the Colorado Department of Public Health & Environment at 303-692-2700 for guidance on determining vaccine viability.

**E. PROTOCOL FOR TESTING THE EMERGENCY STORAGE AND HANDLING PROCEDURES**

- At least once every three months the Vaccine Coordinator, Back-up Coordinator or other responsible individual will:
  - Test the phone numbers for contacts at the alternate storage locations, alarm company, repair service, etc.;
  - Make sure that temporary storage or transport materials are available and ready to use;
  - Update Vaccine Management Plan as needed; and
  - Post plan updates for all staff to read.

# Emergency Vaccine Management Plan

**Initiate Emergency Vaccine Management Plan if any of the following situations are found:**

- Refrigerator Is Too Cold or Too Warm
- Freezer Is Too Warm
- Refrigerator/Freezer Is Malfunctioning (Door won't close securely, Erratic temperatures, etc.)
- There Is a Power Failure

**IMPORTANT!** Follow the steps below:

- Determine why temperature is out of range. Use the attached flow sheets as a guide.
  - NOTE! Erratic temperatures may be resolved by adding additional water bottles or cold packs to the empty spaces in the unit.
  - Keep refrigerator/freezer door closed
  - Monitor temperatures every 30 minutes until temperatures stabilize.
  - Document actions taken on temperature log, or attach document to the temperature log.
  - If temperature in the effected unit has not returned to the acceptable range within 4 hours further steps must be taken to guarantee vaccines remain safely stored.
- Bag and label ALL vaccines in affected unit as QUARANTINED - "Do Not Use".
- Move the vaccines into a unit where they can be stored under proper conditions.
- Contact all vaccine manufacturers and document results of the conversations.
  - Vaccine manufacturers:
    - Sanofi Pasteur: 800-822-2463
    - Berna Products: 800-533-5899 (for typhoid vaccine)
    - GlaxoSmithKline: 888-825-5249
    - Merck: 800-609-4618
    - Wyeth: 800-999-9384
    - MedImmune: 877-633-4411
    - Novartis: 800-244-7668
- Contact Nicole Ortiz in the Colorado Department of Public Health & Environment's Immunization Program at 303-692-2700 for further guidance.
- Document the incident and ALL actions taken on the temperature log sheet and record future actions until incident is resolved.
  - **If unit is Malfunctioning:** Call a repair service. The following repair services offer 24 hour service:
    - [REDACTED], phone [REDACTED]
    - [REDACTED], phone [REDACTED]
  - **If vaccines must be moved to an alternate storage location:** vaccines will be transported to that location before the end of the business day.
    - The alternate storage location is:  
[REDACTED]  
Contact Name: [REDACTED]  
Address: [REDACTED]  
Phone Number: [REDACTED]

- **Verify the following before off-site transfer of our vaccines:**
  - The alternate refrigerator/freezer is maintaining the proper temperature for storage of vaccines.
  - There is enough room for proper storage of vaccine in the alternate refrigerator/ freezer.
  - The alternate location has adequate power or a generator.
  - Vaccines will be packed and transported as described in Job Aid 8.1 Packing Vaccines for Transport on pages 11 and 12.

**IMMUNIZATION PROGRAM CONTACTS:**

Colorado Immunization Program (CIP):

- Nicole Ortiz, Vaccine Manager (303) 692-2700
- Nurse Consultant for Region: \_\_\_\_\_ ( ) - \_\_\_\_\_.

Our Vaccine Management Plan is updated yearly, or as staff changes and is verified by the signature below.

POLICY UPDATED: \_\_\_\_/\_\_\_\_/\_\_\_\_ PRINT NAME AND TITLE: \_\_\_\_\_

AUTHORIZING SIGNATURE: \_\_\_\_\_

POLICY UPDATED: \_\_\_\_/\_\_\_\_/\_\_\_\_ PRINT NAME AND TITLE: \_\_\_\_\_

AUTHORIZING SIGNATURE: \_\_\_\_\_

POLICY UPDATED: \_\_\_\_/\_\_\_\_/\_\_\_\_ PRINT NAME AND TITLE: \_\_\_\_\_

AUTHORIZING SIGNATURE: \_\_\_\_\_

POLICY UPDATED: \_\_\_\_/\_\_\_\_/\_\_\_\_ PRINT NAME AND TITLE: \_\_\_\_\_

AUTHORIZING SIGNATURE: \_\_\_\_\_

Practice/Clinic name: \_\_\_\_\_

## Staff Training on Vaccine Management Plan

The Centers for Disease Control and Prevention requires primary and back-up immunization coordinators receive training on vaccine storage and handling. The lead person responsible for VFC status screening must receive training on screening and documenting a child's VFC status.

**RESOURCES:** The following training activities meet these requirements:

- **CDC's You Call the Shots** – There are two training modules: Vaccine Storage and Handling and Vaccines for Children (VFC) available from the CDC. To access these training courses, follow the instructions found at: [www.coloradovfc.com](http://www.coloradovfc.com), under the VFC Job Aids link. Look for the "You Call the Shots Training Module Instructions." Continuing education credits are available for each module.
- **VFC Provider Compliance Site Visit:** If the provider receives a site visit, the site visit meets the training requirement. The primary vaccine coordinator should sign the site visit questionnaire. Staff participating in the site visit should enter their name, the date of the visit and note that it was a site visit on the Clinic Training Plan.

Providers may use the tracking document below to record the initial and annual trainings. Present this record when requested by state or local public health staff. Have record available during provider compliance site visits.

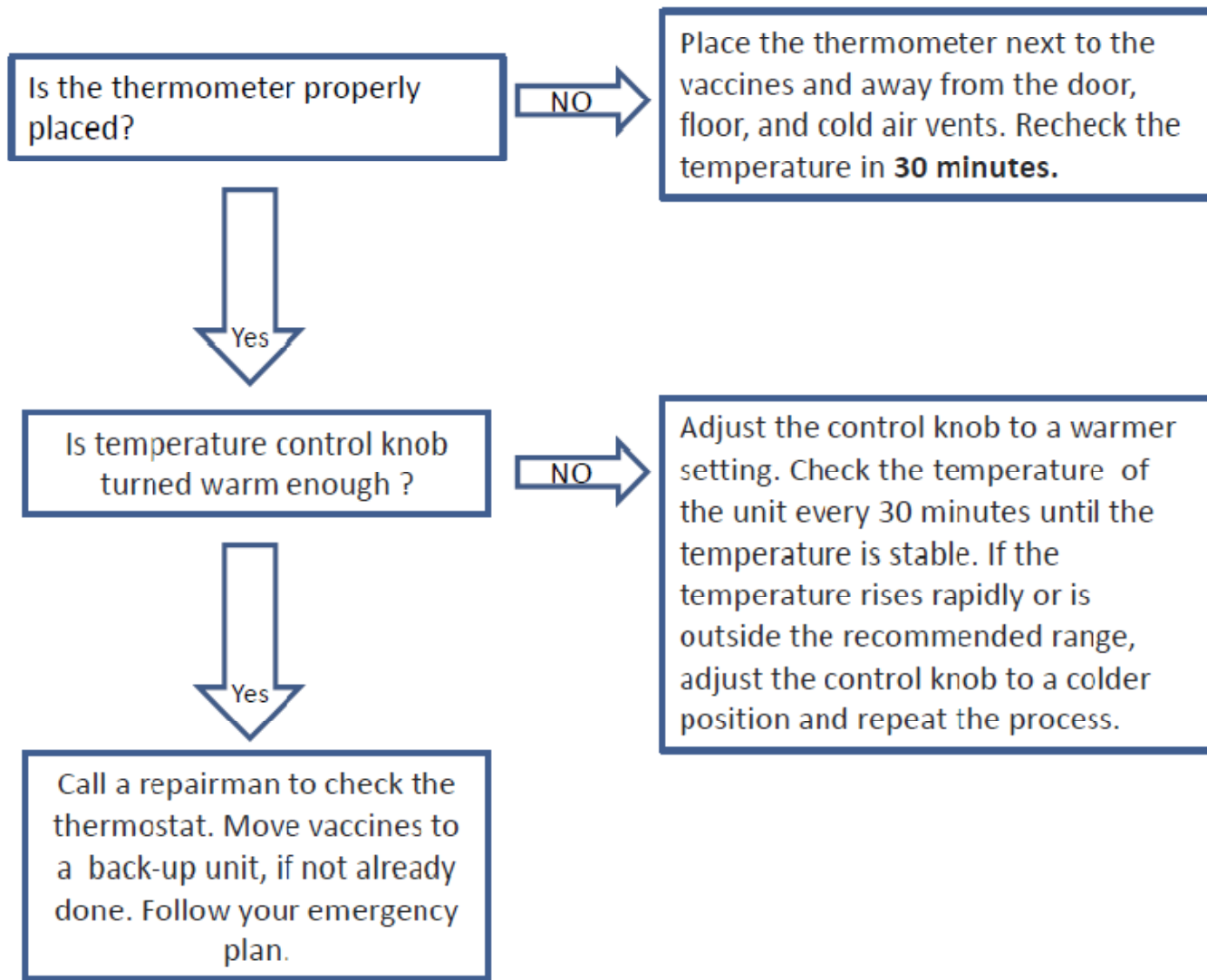
### Training Records (please use additional pages if necessary):

Staff Name	Training Type/Name	Initial Training Date	Additional Training Dates (minimum annual training required)			

The State must document annual training completion to the CDC for each provider site enrolled in the Vaccines for Children program.

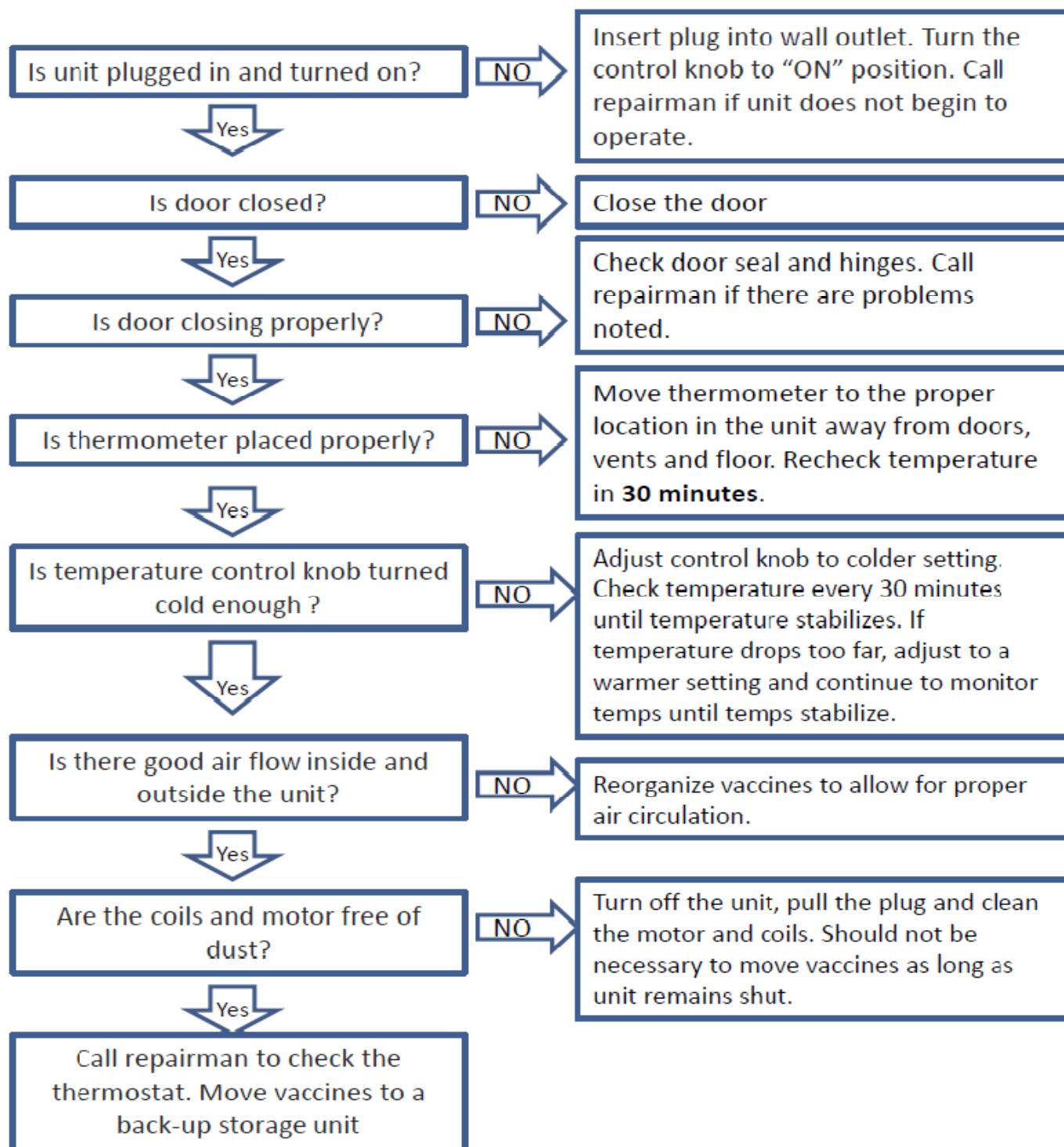
## Vaccine Storage Unit is Too Cold!

Take immediate Action to protect the vaccines! Do NOT allow vaccines to remain in a non-functioning unit for an extended period of time while attempting to correct the problem. Activate your Emergency Vaccine Storage Plan if needed.



## Vaccine Storage Unit is Too Warm!

Take immediate Action to protect the vaccines! Do NOT allow vaccines to remain in a non-functioning unit for an extended period of time while attempting to correct the problem. Activate your Emergency Vaccine Storage Plan if needed.



## Job Aid 8.1 Packing Vaccines for Transport

### Guidelines for temporary storage/transporting of vaccines

The procedure outlined below will keep all vaccines (including varicella-containing vaccines\*) within recommended storage temperatures for 12 hours during transport and/or storage at room temperature. It will also maintain recommended temperatures if the cooler is exposed to outside temperatures as low as -4°F for one of those 12 hours.

\* The varicella-containing vaccine must be refrigerated (and NOT re-frozen) after transport, if freezer temperatures cannot be maintained. Be sure that the refrigerators have maintained temperatures between 35° F and 46° F (2° C - 8° C) for at least 3 to 5 days.

#### Assemble Packing Supplies

1. **Cooler:** Use a hard plastic insulated Igloo-type cooler with at least 2-inch walls. Attach a "Vaccines: Do Not Freeze" label to the cooler.
2. **"Conditioned" cold packs:** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and the packs look like they have been "sweating." Cold packs that are not conditioned can freeze refrigerated vaccine. **Do not use dry ice.**
3. **Thermometer:** Prepare the thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine.
4. **Packing materials:** Use at least two 2 inch layers of bubble wrap, or similar packing material. Not enough packing material can cause refrigerated vaccine to freeze.



### Pack the vaccine

#### 1. Cold Packs

Spread conditioned cold packs to cover only half of the bottom of the cooler.



#### 2. Bubble Wrap

#### & Thermometer

Completely cover the cold packs with a two inch layer of bubble wrap. Place the thermometer/probe on top of the bubble wrap directly above a cold pack.



#### 3. Vaccine

Stack layers of vaccine boxes on the bubble wrap. Do not let boxes touch the ice packs.



#### 4. Bubble Wrap

Completely cover the vaccine with another 2-inch layer of bubble wrap.



#### 5. Cold Packs

Spread "conditioned" cold packs to cover only half the bubble wrap. Make sure the cold packs do not touch the vaccine boxes.



#### 6. Form & Display

Fill the cooler to the top with bubble wrap. Place the thermometer display and the Vaccine transfer form on top.



**As soon as you reach your destination, or before returning the vaccine(s) to the storage unit(s) check the temperature!**

**If the vaccine temperature is:**

- Between 35°F and 46°F, place the vaccines in the refrigerator, including all vaccines previously frozen. Label previously frozen vaccines containing varicella to be used within 72 hours.
- Below 32°F or above 46°F, label the vaccines "DO NOT USE," place them in the refrigerator, and contact the VFC program immediately at: [cdphe\\_vfc@state.co.us](mailto:cdphe_vfc@state.co.us).

## Additional Information

### Packing Diluents

1. Diluents should be transported with their corresponding vaccines so there are equal numbers of vaccine and diluents vials for reconstitution
2. Diluents that contain antigen should be transported with their corresponding vaccine at refrigerator temperature
3. Diluents that *do not* contain antigen can be transported at room temperature or refrigerator temperature
4. Diluents normally stored at room temperature should be refrigerated in advance of transportation with refrigerated vaccines

### Packing Varicella-Containing Vaccines

Varicella-containing vaccines may be transported at refrigerated temperature (35°- 46° Fahrenheit, 2°-8° Celsius) for up to 72 hours prior to reconstitution. Although CDC does not recommend transport of frozen vaccine, in the event of an emergency, transport can be accomplished with a portable unit that maintains a temperature between -58°F and +5°F (-50°C and -15°C).

Instruction for the packing and transport of frozen vaccine:

1. Place enough ice packs to cover the bottom of the cooler.
2. Place the vaccine boxes directly on top of the ice packs. **NOTE:** DO NOT freeze the diluents.
3. Place a calibrated thermometer in the container as close as possible to the vaccine.
4. Place another layer of ice packs directly on top of the vaccine boxes.
5. Use packing material to keep cooler contents from shifting. DO NOT place bubble wrap between the vaccine boxes and the ice packs.
6. Record on the transport log:
  - a. The time the vaccine was removed from the storage unit and placed in the container.
  - b. The temperature during transport.
7. **Immediately** upon arrival at the alternate storage facility:
  - a. Place the vaccine in a freezer. Any freezer that has a separate sealed door and reliably maintains a temperature between -58°F and +5°F (-50° C and -15 °C) is acceptable for storage of varicella-containing vaccines.
  - b. Document the time and the temperature when the vaccine was removed from the container and placed in the freezer.
  - c. Label the vaccine "Quarantined: Do Not Use."
  - d. **Contact the manufacturer at 1-800-637-290 for further guidance**, as this is considered a temperature excursion.
  - e. Do not discard vaccine without contacting the Colorado Immunization Section ([cdphe\\_vfc@state.co.us](mailto:cdphe_vfc@state.co.us)) and the manufacturer for guidance.
8. Use of dry ice is not recommended, even for temporary storage or emergency transport.

Adapted from the California VFC Program ([www.eziz.org](http://www.eziz.org)) for the Colorado Department of Public Health and Environment Immunization Section ([www.coloradoimmunizations.com](http://www.coloradoimmunizations.com))



Colorado Department  
of Public Health  
and Environment

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